

Bicalutamide Tablets USP 50 mg**Safety Data Sheet Bicalutamide Tablets USP 50 mg**

Size: HDPE Bottle 30's NDCs 72578-215-06,

Size: HDPE Bottle 100's 72578-215-01.

Date of issue: 10/28/2025

Version: 1.0

1.1. Product Identifier**Product Name:** Bicalutamide Tablets USP 50 mg**1.2. Intended Use of the Product****Use of the substance/mixture:** Pharmaceutical.**1.3. Name, Address, and Telephone of the Responsible Party****Company**Viona Pharmaceutical Inc.
20, commerce drive,
Ste 340
Cranford, New Jersey 07016
USA**Manufacturer**Pinnacle Life Science Pvt. Ltd.
Khasra No. 1331, 1332 and 1335,
Village
Manpura, Tehsil Baddi, Distt.
Solan,
(H.P.)-174101, India**1.4. Emergency Telephone Number****Emergency Number** : 1-800-424-9300 Call CHEMTREC Day or Night

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, it is exempt from labeling, as defined in the 29 CFR 1910.1200(b)(5)(iii).

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii).

Section 2. HAZARD(S) IDENTIFICATION

Dose and Administration	The recommended dose for bicalutamide therapy in combination with an LHRH analog is one 50 mg tablet once daily (morning or evening) 50 mg tablets
Adverse Effects	Adverse reactions that occurred in more than 10% of patients receiving bicalutamide plus an LHRH-A were: hot flashes, pain (including general, back, pelvic and abdominal), asthenia, constipation, infection, nausea, peripheral edema, dyspnea, diarrhea, hematuria, nocturia and anemia
Overdosage	In the management of an overdose with bicalutamide, vomiting may be induced if the patient is alert. It should be remembered that, in this patient population, multiple drugs may have been taken. Dialysis is not likely to be helpful since bicalutamide is highly protein bound and is extensively metabolized. General supportive care, including frequent monitoring of vital signs and close observation of the patient, is indicated
Pregnancy Comments	Bicalutamide is contraindicated for use in pregnant women because it can cause fetal harm. Bicalutamide is not indicated for use in females. There are no human data on the use of bicalutamide in pregnant women. In animal reproduction studies, oral administration of bicalutamide to pregnant rats during organogenesis caused abnormal development of reproductive organs in male fetuses at exposures approximately 0.7 to 2 times the human exposure at the recommended dose
Pregnancy Category	Category X

Section 3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Exposure Limit	CAS No.
Principle Component: Bicalutamide	50 mg/day	90357-06-5
Inactive ingredients:		

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Lactose monohydrate	Not Found	10039-26-6
Sodium starch glycolate	Not Found	9063-38-1
Povidone K-25	Not Found	9003-39-8
Magnesium stearate	Not Found	557-04-0
Opadry white 02B58839	Not Found	HPMC-E464
		TITANIUM-E171
		MACROGEL/PEG-E1521.

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Gently wash with plenty of soap and water. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if redness, pain, or irritation occurs.

First-aid Measures After Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: Suspected of damaging fertility or the unborn child.

Symptoms/Injuries After Inhalation: If tablet is crushed: Dust may cause respiratory irritation.

Symptoms/Injuries After Skin Contact: If tablet is crushed: Dust may cause skin irritation.

Symptoms/Injuries After Eye Contact: If tablet is crushed: Dust may cause serious eye irritation.

Symptoms/Injuries After Ingestion: May be harmful if swallowed.

Chronic Symptoms: Bicalutamide may cause fetal harm when administered to pregnant women.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

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5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Use only as directed.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain and collect as any solid.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Minimize generation of dust. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store at 20°C to 25°C (68°F to 77°F) Excursion permitted between 15°C to 30°C (59°F to 86°F) (see USP controlled Room Temperature)

Incompatible Products: Strong acids. Strong bases. Strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Titanium dioxide (13463-67-7)		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA IDLH	US IDLH (mg/m ³)	5000 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust)
Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA (mg/m ³)	10 mg/m ³ (MW>200, aerosol)

8.2. Exposure Controls

Appropriate Engineering Controls

: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Protective goggles. Gloves. Protective clothing.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

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Hand Protection	: Wear chemically resistant protective gloves.
Eye Protection	: Chemical goggles or safety glasses.
Skin and Body Protection	: Wear suitable protective clothing.
Respiratory Protection	: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn.
Environmental Exposure Controls	: Do not allow the product to be released into the environment.
Consumer Exposure Controls	: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Tablet
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available.

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO₂). Metal oxides. Hydrogen fluoride. Nitrogen oxides. Sulfur oxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

2-Pyrrolidinone, 1-ethenyl-, homopolymer (9003-39-8)	
LD50 Oral Rat	100000 mg/kg
Magnesium stearate (557-04-0)	
LD50 Oral Rat	> 2000 mg/kg
LC50 Inhalation Rat	> 2 mg/l/4h
Cellulose hydroxypropyl methyl ether (9004-65-3)	
LD50 Oral Rat	>= 4000 mg/kg
Titanium dioxide (13463-67-7)	
LD50 Oral Rat	> 10000 mg/kg
Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	47000 mg/kg

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LD50 Dermal Rabbit	> 20 ml/kg
Skin Corrosion/Irritation: Not classified	
Serious Eye Damage/Irritation: Not classified	
Respiratory or Skin Sensitization: Not classified	
Germ Cell Mutagenicity: Not classified	
Carcinogenicity: Not classified	
2-Pyrrolidinone, 1-ethenyl-, homopolymer (9003-39-8)	
IARC group	3
Titanium dioxide (13463-67-7)	
IARC group	2B
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: May damage fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: If tablet is crushed: Dust may cause respiratory irritation.

Symptoms/Injuries After Skin Contact: If tablet is crushed: Dust may cause skin irritation.

Symptoms/Injuries After Eye Contact: If tablet is crushed: Dust may cause serious eye irritation.

Symptoms/Injuries After Ingestion: May be harmful if swallowed.

Chronic Symptoms: Bicalutamide may cause fetal harm when administered to pregnant women.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity No additional information available.

12.2. Persistence and Degradability No additional information available.

12.3. Bioaccumulative Potential No additional information available.

12.4. Mobility in Soil No additional information available.

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport.

14.2. In Accordance with IMDG Not regulated for transport.

14.3. In Accordance with IATA Not regulated for transport.

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations Not applicable

15.2 US State Regulations Not applicable

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.